TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
812.28(c); waivers	10	1	10	1	10
812.35 and 812.150; application supplements	654	5	3,270	6	19,620
812.36(c); treatment IDE applications	1	1	1	120	120
812.36(f); treatment IDE reports	1	1	1	20	20
812.150; non-significant risk study reports	1	1	1	6	6
Total			5,513		53,897

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate of the average reporting burden is based on our continued experience with the information collection. We have adjusted the currently approved burden to reflect an increase we attribute to Agency rulemaking that has become effective (OMB control number 0910–AG48) since our last evaluation. Regulations in part 812 were amended to provide for reporting associated with the acceptance of data from clinical investigations conducted outside the United States.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
812.2(c)(3); records regarding leftover specimens not individually identifiable used in certain studies	700	1	700	4	2,800
812.28(d); records for clinical investigations conducted outside U.S	1,500	1	1,500	1	1,500
812.140; retention of records	1,249	3.09	3,865	1.9937	7,706
Total					12,006

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the guidance document ''Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' (April 2006), available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not,* FDA communicates its enforcement policy with regard to the informed consent regulations (as required by section 520(g) of the FD&C Act and 21 CFR part 50) for in vitro diagnostic device studies that are conducted using leftover specimens and that meet the criteria for exemption from IDE regulation at 21 CFR 812.2(c)(3). We include burden that may be attributable to FDA recommendations that sponsors of studies document certain information, in table 2, row 1. We have otherwise adjusted our estimate upward of the average recordkeeping burden attributable to provisions in part 812 to reflect those requirements associated with clinical investigations conducted outside the United States, and in recognition of the required retention period for records.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09751 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0131]

Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients With Type 2 Diabetes Mellitus; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus.'' This guidance provides recommendations for feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with Type 2 Diabetes Mellitus. These medical devices are intended to therapeutically reduce glycated hemoglobin in Type 2 Diabetes Mellitus patients independent of medication (*e.g.,* insulin) delivery.

DATES: The announcement of the guidance is published in the **Federal Register** on May 6, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0131 for ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2604, Silver Spring, MD 20993–0002, 240–402–6510.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides recommendations for the design of feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with Type 2 Diabetes Mellitus (T2DM). T2DM is a metabolic disorder that is characterized by high blood sugar levels, insulin resistance, and relative lack of insulin. In 2020, it was estimated that 10.5 percent of the United States population, or roughly 34.2 million Americans, have diabetes and that T2DM accounts for 90 percent to 95 percent of all diabetes cases.[1]

Due to the prevalence of T2DM in the United States, many medical device manufacturers and researchers seek to develop therapeutic medical devices that are intended to improve glycemic control in patients with T2DM. Historically, there have been several legally marketed devices that help patients manage T2DM, including medical devices intended to measure or monitor blood sugar (*e.g.,* blood glucose monitors, continuous glucose monitors) or dose and deliver insulin (*e.g.,* insulin pens, pumps, syringes). Medical devices that are therapeutically intended to improve glycemic control in patients with T2DM are an increasing area of interest. Manufacturers frequently request the Agency's feedback regarding feasibility and early feasibility clinical studies for these medical devices. This guidance represents the Agency's initial thinking on feasibility and early feasibility clinical studies for these medical devices. FDA's recommendations may change as more information becomes available.

A notice of availability of the draft guidance appeared in the **Federal Register** of May 20, 2021 (86 FR 27438). FDA considered comments received and revised the guidance as appropriate in response to the comments, including revisions to clarify the scope of devices included in the guidance and revisions to clarify or provide examples of certain terminology used in the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with T2DM. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological

[1] Center for Disease Control, National Diabetes Statistics Report 2020: Estimates of Diabetes and its Burden in the United States, available at *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.*

Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19045 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
812	Investigational Device Exemption	0910–0078
''Requests for Feedback on Medical Device Submissions: The Q-Submission Program''.	Q-submissions; Pre-submissions	0910–0756
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: April 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09738 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Virtual Stakeholder Listening Session in Preparation for the 75th World Health Assembly

Time and date: The session will be held on Friday, May 13, 2022, from 10:00 a.m.–12:00 p.m. Eastern Time (ET).

Place: The session will be held virtually, and registration is required. Please RSVP by May 6, 2022 by sending your full name, email address, and organization to *OGA.RSVP@hhs.gov.* OGA encourages early registration.

Status: Open, but requiring RSVP to *OGA.RSVP@hhs.gov* to register.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 75th World Health Assembly—will hold an informal Stakeholder Listening Session on Friday, May 13, 10:00 a.m.–12:00 p.m. ET. The listening session will be held virtually, and the meeting link will be shared with registered participants prior to the session.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation to the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by agenda items to be discussed at the 75th World Health Assembly. The U.S. Government will consider contributions received from the stakeholders as it develops the U.S. positions.

The listening session will be organized by agenda item, and participation is welcome from stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 75th World Health Assembly can be found at this website: *https://apps.who.int/gb/e/e_wha75.html.*

RSVP: Registration is required for the event. Please send your full name, email address, and organization to *OGA.RSVP@hhs.gov* to register. Please RSVP no later than Friday, May 6, 2022.

Written comments are welcome and encouraged, even if you are planning on attending the virtual session. Please send written comments to the email address: *OGA.RSVP@hhs.gov.*

We look forward to hearing your comments related to the 75th World Health Assembly agenda items.

Dated: May 2, 2022.

Susan C. Kim,

Chief of Staff, Office of Global Affairs.

[FR Doc. 2022–09710 Filed 5–5–22; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Study Section.

Date: June 9–10, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205-H, Bethesda, MD 20892, (301) 827–7969, *Pintuccig@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and